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In re: Waldon et al. Serial No.: 10/029,423 Filed: December 20, 2001

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In the Claims:

- 1. (Currently Amended) A pharmaceutical composition for the treatment of female sexual dysfunction, said composition comprising:
 - a therapeutically effective amount of an estrogenic compound;
 - a therapeutically effective amount of an androgenic compound;
 - a therapeutically effective amount of a vasodilation compound; and
- a pharmaceutically acceptable carrier, with the proviso that the pharmaceutically acceptable carrier is not a buccal dosage unit.
- 2. (Original) The pharmaceutical composition according to Claim 1, wherein the estrogenic compound is selected from the group consisting of estrone, 17α -estradiol, 17β -estradiol, equilin, 17α -dihydroequilin, 17β -dihydroequilin, equilenin, 17α -dihydroequilenin, 17β -dihydroequilenin, 17α -dehydroestradiol, ethinyl estradiol, estradiol valerate, 6-OH equilenin, 6-OH 17α -dihydroequilenin, 6-OH 17β -dihydroequilenin, and mixtures, conjugates and salts thereof.
- 3. (Original) The pharmaceutical composition according to Claim 1, wherein the androgenic compound is selected from the group consisting of methyltestosterone, androsterone, androsterone acetate, androstenedione, androstenediol, androsterone propionate, androsterone benzoate, androsteronediol, androsteronediol-3acetate, androsteronediol-17-acetate, androsteronediol 3,17-diacetate, androsteronediol-17-benzoate, androsteronediol-3-acetate-17-benzoate, androsteronedione, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, derdicale, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, oxymetholone, stanozolol, testosterone, 17α-methyl-19-nortestosterone, testosterone decanoate, 4-dihydrotestosterone, 5α -dihydrotestosterone, testolactone, pharmaceutically acceptable esters and salts thereof, and combinations of any of the foregoing.

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- 4. (Previously presented) The pharmaceutical composition according to Claim 1, wherein the vasodilation compound is an alpha adrenergic antagonists.
- 5. (Original) The pharmaceutical composition according to Claim 4, wherein the alpha adrenergic antagonist is phentolamine mesylate or phentolalmine hydrochloride.
- 6. (Original) The pharmaceutical composition according to Claim 4, wherein the vasodilation compound further comprises apomorphine.
- 7. (Original) The pharmaceutical composition according to Claim 1, further comprising a therapeutically effective amount of a progestin compound.
- 8. The pharmaceutical composition according to Claim 7, (Original) wherein the progestin compound is selected from the group consisting of desogestrel, ethynodiol diacetate, medroxyprogesterone, levonorgestrel, dydrogesterone, medroxyprogesterone acetate, hydroxyprogesterone norethindrone, caproate, norethindrone acetate, norethynodrel, allylestrenol, 19-nortestosterone, lynoestrenol, quingestanol acetate, medrogestone, norgestrienone, dimethisterone, ethisterone, cyproterone acetate, chlormadinone acetate, megestrol acetate, norgestimate, norgestrel, desogestrel, trimegestone, gestodene, nomegestrol acetate, nomegestrol progesterone, 5αpregnan-3β, 20α-diol sulfate, 5α-pregnan-3β, 20β-diol sulfate, 5α-pregnan-3β-ol-20-one, 16,5α-pregnen-3β-ol-20-one, 4-pregnen-20β-ol-3-one-20-sulfate, acetoxypregnenolone, anagestone acetate, cyproterone, dihydrogesterone, flurogestone acetate, gestadene, hydroxyprogesterone hydroxymethylprogesterone, hydroxymethyl acetate, progesterone acetate, 3-ketodesogestrel, megestrol, melengestrol acetate, norethisterone and mixtures thereof.
- 9. (Currently Amended) A pharmaceutical composition for the treatment of female sexual dysfunction in a pre-menopausal female, said composition comprising:
 - a therapeutically effective amount of an androgenic compound;
 - a therapeutically effective amount of a vasodilation compound; and

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a pharmaceutically acceptable carrier, with the proviso that the pharmaceutically acceptable carrier is not a buccal dosage unit.

- 10. The pharmaceutical composition according to Claim 9, (Original) wherein the androgenic compound is selected from the group consisting of methyltestosterone, androstenedione, androstenediol, androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androsteronediol, androsteronediol-3acetate, androsteronediol-17-acetate, androsteronediol 3,17-diacetate, androsteronediol-17-benzoate, androsteronediol-3-acetate-17-benzoate, androsteronedione, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, derdicale, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, oxymetholone, stanozolol, testosterone, 17α-methyl-19-nortestosterone, testosterone decanoate, 4-dihydrotestosterone, 5α-dihydrotestosterone, testolactone, pharmaceutically acceptable esters and salts thereof, and combinations of any of the foregoing.
- 11. (Original) The pharmaceutical composition according to Claim 9, wherein vasodilation compound is an alpha adrenergic antagonist.
- 12. (Original) The pharmaceutical composition according to Claim 11, wherein the alpha adrenergic antagonist is phentolamine mesylate or phentolamine hydrochloride.
- 13. (Original) The pharmaceutical composition according to Claim 12, wherein the vasodilation compound further comprises apomorphine.
- 14. (Original) The pharmaceutical composition according to Claim 9, further comprising a therapeutically effective amount of a progestin compound.

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- The pharmaceutical composition according to Claim 15, 15. (Original) wherein the progestin compound is selected from the group consisting of desogestrel, ethynodiol diacetate. medroxyprogesterone, levonorgestrel, dydrogesterone, medroxyprogesterone acetate, hydroxyprogesterone caproate, norethindrone, norethindrone acetate, norethynodrel, allylestrenol, 19-nortestosterone, lynoestrenol, quingestanol acetate, medrogestone, norgestrienone, dimethisterone, ethisterone, cyproterone acetate, chlormadinone acetate, megestrol acetate, norgestimate, norgestrel, desogestrel, trimegestone, gestodene, nomegestrol acetate, nomegestrol progesterone, 5αpregnan-3β, 20α-diol sulfate, 5α-pregnan-3β, 20β-diol sulfate, 5α-pregnan-3β-ol-20-one, 16,5α-pregnen-3β-ol-20-one, 4-pregnen-20β-ol-3-one-20-sulfate, acetoxypregnenolone, anagestone acetate, cyproterone, dihydrogesterone, flurogestone acetate, gestadene, hydroxymethylprogesterone, hydroxymethyl hydroxyprogesterone acetate, progesterone acetate, 3-ketodesogestrel, megestrol, melengestrol acetate, norethisterone and mixtures thereof.
- 16. (Currently Amended) A pharmaceutical formulation for treating female sexual dysfunction comprising:
 - a therapeutically effective amount of an estrogenic compound;
 - a therapeutically effective amount of an androgenic compound;
- a pharmaceutically acceptable carrier, with the proviso that the pharmaceutically acceptable carrier is not a buccal dosage unit; and
- a therapeutically effective amount of a vasodilation compound administered on a performance-on-demand basis.

17-51. (Canceled).

- 52. (New) A pharmaceutical composition for the treatment of female sexual dysfunction, said composition comprising:
 - a therapeutically effective amount of an estrogenic compound;
 - a therapeutically effective amount of an androgenic compound;
 - a therapeutically effective amount of a vasodilation compound; and

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a pharmaceutically acceptable carrier, with the proviso that the pharmaceutically carrier is not a bioerodible polymeric carrier.

- 53. (New) The pharmaceutical composition according to Claim 52, wherein the estrogenic compound is selected from the group consisting of estrone, 17α-estradiol, 17β-estradiol, equilin, 17α-dihydroequilin, 17β-dihydroequilin, equilenin, 17α-dihydroequilenin, 17β-dihydroequilenin, $\Delta^{8,9}$ -dehydroestrone, 17α- $\Delta^{8,9}$ -dehydroestradiol, ethinyl estradiol, estradiol valerate, 6-OH equilenin, 6-OH 17α-dihydroequilenin, 6-OH 17β-dihydroequilenin, and mixtures, conjugates and salts thereof.
- (New) The pharmaceutical composition according to Claim 52, wherein 54. the androgenic compound is selected from the group consisting of methyltestosterone, androsterone, androsterone acetate, androstenedione, androstenediol, androsterone benzoate, androsteronediol, androsteronediol-3-acetate, propionate, androsterone androsteronediol-17-acetate, androsteronediol 3,17-diacetate, androsteronediol-17androsteronediol-3-acetate-17-benzoate, androsteronedione, benzoate, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, derdicale, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, oxymetholone, stanozolol, testosterone, 17α-methyl-19-nortestosterone, testosterone decanoate, 4-dihydrotestosterone, 5α -dihydrotestosterone, testolactone, pharmaceutically acceptable esters and salts thereof, and combinations of any of the foregoing.
- 55. (New) The pharmaceutical composition according to Claim 52, wherein the vasodilation compound is an alpha adrenergic antagonists.
- 56. (New) The pharmaceutical composition according to Claim 55, wherein the alpha adrenergic antagonist is phentolamine mesylate or phentolalmine hydrochloride.

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- 57. (New) The pharmaceutical composition according to Claim 55, wherein the vasodilation compound further comprises apomorphine.
- 58. (New) The pharmaceutical composition according to Claim 52, further comprising a therapeutically effective amount of a progestin compound.
- 59. (New) The pharmaceutical composition according to Claim 58, wherein the progestin compound is selected from the group consisting of desogestrel, dydrogesterone, ethynodiol diacetate, medroxyprogesterone, levonorgestrel, medroxyprogesterone acetate, hydroxyprogesterone caproate, norethindrone, norethindrone acetate, norethynodrel, allylestrenol, 19-nortestosterone, lynoestrenol, medrogestone, norgestrienone, dimethisterone, ethisterone, quingestanol acetate, cyproterone acetate, chlormadinone acetate, megestrol acetate, norgestimate, norgestrel, desogestrel, trimegestone, gestodene, nomegestrol acetate, nomegestrol progesterone, 5αpregnan-3β, 20α-diol sulfate, 5α-pregnan-3β, 20β-diol sulfate, 5α-pregnan-3β-ol-20-one, 16,5α-pregnen-3β-ol-20-one, 4-pregnen-20β-ol-3-one-20-sulfate, acetoxypregnenolone, anagestone acetate, cyproterone, dihydrogesterone, flurogestone acetate, gestadene, hydroxymethylprogesterone, hydroxymethyl hydroxyprogesterone acetate, progesterone acetate, 3-ketodesogestrel, megestrol, melengestrol acetate, norethisterone and mixtures thereof.